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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|------------------------|---------------------|------------------|
| 10/611,593 | 06/30/2003 | Marie-Laure Lesaichere | 6565-66285/RJP | 5201 |

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EXAMINER

YANG, NELSON C

ART UNIT PAPER NUMBER

1641

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/611,593 | Applicant(s) LESAICHERRE ET AL. | |
| | Examiner Nelson Yang | Art Unit 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 17-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>10/02/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group I, claims 1-16 in the reply filed on May 15, 2006 is acknowledged.
2. Claims 17-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 15, 2006.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. With respect to claims 1, 9, it is unclear which portion of the protein would be considered the remaining protein, rendering it unclear where the ligand is actually attached. Furthermore, it is unclear if the protein, once cleaved, would still remain a protein. Clarification would be greatly appreciated.
6. With respect to claim 5, it is unclear whether the cysteine-biotin is actually the ligand, or if it is a means for attaching the ligand. This is also applicable to claim 13. Clarification would be greatly appreciated.
7. The remaining claims are indefinite due to their dependence on an indefinite claim.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claims 1-3, 9, 10 are rejected under 35 U.S.C. 102(a) as being anticipated by Lesaicherre et al [Lesaicherre et al, Intein-mediated biotinylation of proteins and its application in a protein microarray, July 2002, J Am Chem Soc, 124, 8768-8769].

With respect to claim 1, Lesaicherre et al teach fusion proteins with an intein tag at the C-termini (p.8768, col.2), where the proteins were purified and biotinylated (ligand) and cleaved (fig.1) and then spotted directly onto an avidin (affinity receptor)-functionalized slide (support) (p.8768, col.2).

10. With respect to claim 2, the proteins were purified and biotinylated (ligand) and then spotted directly onto an avidin (affinity receptor)-functionalized slide (support) (p.8768, col.2).

11. With respect to claim 3, the proteins were spotted directly onto an avidin-functionalized glass slides (p.8768, col.1).

12. With respect to claim 9, Lesaicherre et al teach the expression of fusion proteins (p.8768, col.1) with an intein tag at the C-termini (p.8768, col.2), where the proteins were purified, biotinylated (ligand) and cleaved by flow through from column loading, where proteins bound to a chitin column (substrate) before cleavage (fig.1) and then spotted directly onto an avidin (affinity receptor)-functionalized slide (support) (p.8768, col.2).

Art Unit: 1641

13. With respect to claim 10, the proteins were purified and biotinylated (ligand) and then spotted directly onto an avidin (affinity receptor)-functionalized slide (support) (p.8768, col.2).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 5-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lesaicherre et al [Lesaicherre et al, Intein-mediated biotinylateion of proteins and its application in a protein microarray, July 2002, J Am Chem Soc, 124, 8768-8769] in view of Duan [US 6,951,742].

With respect to claims 4, 11, Lesaicherre et al teach the expression of fusion proteins (p.8768, col.1) with an intein tag at the C-termini (p.8768, col.2), where the proteins were purified, biotinylated (ligand) and cleaved by flow through from column loading, where proteins bound to a chitin column (substrate) before cleavage (fig.1) and then spotted directly onto an avidin (affinity receptor)-functionalized slide (support) (p.8768, col.2). Lesaicherre et al fail to teach that the proteins are expressed by a pTYB1 expression vector.

Duan, however, teaches the use of pTYB1 vectors to express fusion proteins, and further teach that pTYB1 vectors allow the cloning of a target gene immediately adjacent to the intein cleavage site, which results in the purification of a native target protein without any vector derived extra residues after the cleavage (column 32, lines 52-65).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use a pTYB1 expression vector to express the fusion proteins of Lesaicherre et al, as suggested by Duan et al, in order to allow the cloning of a target gene immediately adjacent to the intein cleavage site, allowing for the purification of a native target protein without any vector derived extra residues after the cleavage.

16. With respect to claim 5, Lesaicherre et al teach that the column is flushed with biotinylated cystein (p.8768, col.2, scheme 1).

17. With respect to claim 12, Lesaicherre et al teach that the proteins were bound to a chitin column (substrate) before cleavage (fig.1).

18. With respect to claim 13, Lesaicherre et al teach that the column is flushed with biotinylated cystein (p.8768, col.2, scheme 1).

19. With respect to claim 14, Lesaicherre et al teach that the proteins were spotted directly onto an avidin-functionalized glass slides (p.8768, col.1).

20. With respect to claim 15, Lesaicherre et al teach that the avidin can be streptavidin (p.8769, col.2, pg.2).

21. With respect to claim 16, Lesaicherre et al teach that the biotinylated proteins were spotted directly onto an avidin-functionalized glass slides (p.8768, col.1).

22. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lesaicherre et al [Lesaicherre et al, Intein-mediated biotinylateion of proteins and its application in a protein microarray, July 2002, J Am Chem Soc, 124, 8768-8769] in view of Duan [US 6,951,742], and further in view of Cass et al [US 6,312,906].

With respect to claim 6, Lesaicherre et al teach the expression of fusion proteins (p.8768, col.1) with an intein tag at the C-termini (p.8768, col.2), where the proteins were purified, biotinylated (ligand) and cleaved by flow through from column loading, where proteins bound to a chitin column (substrate) before cleavage (fig.1) and then spotted directly onto an avidin (affinity receptor)-functionalized slide (support) (p.8768, col.2). Lesaicherre et al fail to teach that the avidin is bound to the surface through an epoxy silane compound.

Cass et al, however, teach avidin coating on glass chips functionalized with trimethoxythiopropylsilane (column 17, lines 40-65). Cass et al further teach that using epoxy silane is inexpensive and provides a dense array of monolayers (column 10, lines 15-25).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention of Lesaicherre et al to use coat avidin onto epoxy silane coated glass supports, as suggested by Cass et al, in order to provide an inexpensive way of providing a dense array of monolayers.

23. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lesaicherre et al [Lesachierre et al, Intein-mediated biotinylateion of proteins and its application in a protein microarray, July 2002, J Am Chem Soc, 124, 8768-8769] in view of Duan [US 6,951,742], and in view of Cass et al [US 6,312,906], and further in view of Nygren et al [US 4,588,624].

With respect to claim 7, Lesaicherre et al teach the expression of fusion proteins (p.8768, col.1) with an intein tag at the C-termini (p.8768, col.2), where the proteins were purified, biotinylated (ligand) and cleaved by flow through from column loading, where proteins bound to a chitin column (substrate) before cleavage (fig.1) and then spotted directly onto an avidin

Art Unit: 1641

(affinity receptor)-functionalized slide (support) (p.8768, col.2). Lesaichere et al fail to teach that the avidin is bound to the surface through an epoxy silane such as glycidoxypopyl trimethoxysilane.

Nygren et al, however, teach the use of glycidoxypopyl trimethoxysilane (column 4, example 2), and further teach that it helps provide biocompatible surfaces (column 2, lines 20-32), which would reduce clotting of samples such as blood (column 5, example A).

Therefore, it would have been obvious in the method of Lesaichere et al, Duan, and Cass et al, to use glycidoxypopyl trimethoxysilane to coat the glass, prior to addition of avidin, in order to create a biocompatible surface that would reduce clotting of samples such as blood.

24. With respect to claim 8, Lesaichere et al teach that the avidin can be streptavidin (p.8769, col.2, pg.2).

Conclusion

25. No claims are allowed.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1641

27. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nelson Yang
Patent Examiner
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